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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,851	05/28/2002	Horst Rapp	HMN 2 0021	8437

7590 11/17/2004

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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/031,851

**Applicant(s)**

RAPP ET AL.

**Examiner**

Shaojia A. Jiang

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on August 9, 2004, July 9, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 9, 2004 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed August 9, 2004, and amendment and response to the Final Office Action (dated April 7, 2004), filed July 9, 2004 wherein claims 1-20 have been amended.

Currently, claims 1-20 are pending in this application.

Claims 1-20 as amended now are examined on the merits herein.

Applicant's amendment amending claims 1-20, filed July 9, 2004 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of scope of enablement for any "diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases" of record stated in the Office Action dated April 7, 2004 has been fully considered and is found persuasive to overcome the rejection since the particular skin diseases have been recited. Therefore, the said rejection is withdrawn.

Applicant's amendment filed on July 9, 2004 with respect to the rejection of claims 1-7 and 9-20 made under 35 U.S.C. 112 second paragraph for the use of the

Art Unit: 1617

indefinite recitations, i.e., "derivatives" and "decomposition products" of record stated in the Office Action dated April 7, 2004 have been fully considered and found persuasive to remove the rejection since these indefinite recitations have been removed. Therefore, the said rejection is withdrawn.

As pointed out in the previous Office Action (September 22, 2003), the recitation, "A medicament" in claim 20 will be examined as a pharmaceutical composition for the following reason. According to the ordinary and customary meaning of "medicament" provided by a dictionary: "An agent that promotes recovery from injury or ailment; medicine", and medicine is also defined as "a drug or other agent used to treat disease or injury" (see the definitions of medicament and medicine provided by the American Heritage Dictionary, Second College Edition, 1982, page 781, PTO-892). Thus, the recitation, "A medicament", would be interpreted herein as a pharmaceutical agent, a drug, or a pharmaceutical composition.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 as amended now are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

Art Unit: 1617

as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted July 9, 2004 with respect to these amended claims has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for treating the particular disease "tinea pedis". Nowhere can the particular disease "tinea pedis" be found in the specification.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent

Art Unit: 1617

protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 20 recite the broad recitation "herpes simplex virus" and the claim also recite "including" the particular herpes which is the narrower statement of the range/limitation.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Wakeman (3,317,540, of record).

Wakeman discloses that tosylchloriaamide(s) and its known derivatives are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection (see

Art Unit: 1617

col.1 and col.3 lines 53-56). Wakeman discloses the pharmaceutical compositions of tosylchloriaamide(s) in a form, a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O?W or W/O-emulsion (see col. 2 line 32 to col.3 38).

Thus, Wakeman anticipates claim 20.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by DE 197 12 565 (of record).

DE 197 12 565 discloses that tosylchloriaamide(s) and its known derivatives such as Chloramin T are useful in a pharmaceutical composition by topical administration to skin broadly and hair and thus useful in treating skin diseases herein (see Table at page 5 and claims 1-16). DE 197 12 565 also discloses the effective amounts of the pharmaceutical compositions of tosylchloriaamide(s) (see Table at page 5 and claims therein).

Thus, DE 197 12 565 anticipates claim 20.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Vandeveld et al (WO 91/07876, of record).

Vandeveld et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandeveld et al.

Art Unit: 1617

discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-13 at page 9-20).

Thus, Vandeveld anticipates claim 20.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Harwardt et al (DE 41 37 544, of record).

Harwardt et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4). Thus, Harwardt anticipates claim 20.

As indicated above, the recitation, "A medicament" in claim 20 will be examined as a pharmaceutical composition. Note that it is well settled that "intended use" of a composition or product, e.g., treating disease of the skin, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.



Art Unit: 1617

Note that Applicant also admits that the rejections under 35 U.S.C. 102(b) of record in the previous Office Action are applicable to composition claims (see Applicant's arguments filed July 9, 2004).

Therefore, the rejections of claim 20 under 35 U.S.C. 102(b) of record are maintained and adhered to.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakeman (3,317,540, of record).

Wakeman discloses that tosylchloriaamide(s) and its known derivatives are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection (see col.1 and col.3 lines 53-56). Wakeman discloses the pharmaceutical compositions of tosylchloriaamide(s) and their salts in a form, a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O?W or W/O-emulsion (see col. 2 line 32 to col.3 38). Saito et al. discloses that the particular adrenal enzyme inhibitor, trilostane, is useful in the pharmacological treatment of Cushing's syndrome by

Art Unit: 1617

reducing the steroid production in the patients showing severe hypertension and diabetes mellitus. See title and the English abstract of the Japanese journal article.

Wakeman does not expressly disclose the employment of tosylchloriaamide(s), in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein, because tosylchloriaamide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection according to Wakeman. It is also well-known that the many instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus are caused by microorganisms and/or accompanied by microorganisms.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloriaamide(s) and their salts, the known antiseptics and disinfecting agents would have beneficial therapeutic effects and usefulness in methods of treating instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus, by antiseptic action and disinfecting the affected skin area through killing and destroying microorganisms.

Art Unit: 1617

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandeveld et al (WO 91/07876, of record).

Vandeveld et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandeveld et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-13 at page 9-20).

Vandeveld et al. does not expressly disclose the employment of tosylchloriaamide(s), in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein, because tosylchloriaamide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly

Art Unit: 1617

and hair and methods of treating skin diseases therein such as retrovirus according to Vandeveld et al.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloriaamide(s) and their salts, being known in treating skin retrovirus, would have beneficial therapeutic effects and usefulness in methods of treating herpes simplex virus.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harwardt et al (DE 41 37 544, of record).

Harwardt et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4).

Harwardt et al. does not expressly disclose the employment of tosylchloriaamide(s), in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein.

Art Unit: 1617

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein, because tosylchloriaamide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus according to Harwardt et al.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloriaamide(s) and their salts, being known in treating skin retrovirus, would have beneficial therapeutic effects and usefulness in methods of treating herpes simplex virus.

Applicant's arguments filed July 9, 2004 with respect to this rejections made under 35 U.S.C. 102(b) of record in the previous Office Action April 7, 2004 have been considered but are moot in view of the new ground(s) of rejection above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The

Art Unit: 1617

fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.  
Primary Examiner, AU 1617  
November 10, 2004